III. Remarks

A. Status of the Application

Claims 20, 25 and 36 are amended in the present paper. No claims are added or cancelled in the present paper. Prior to the present paper, Claims 1 –10 were cancelled and claims 11 – 14 were withdrawn. Thus, claims 15 – 44 are pending herein. Reconsideration of this application in light of the following remarks is respectfully requested.

B. Amendments to the Claims

Claims 20 and 25 have been amended herein to describe a device that includes a tubular member having a liquid inlet/outlet and an opening, and a base member contained through the opening. Further, means for drawing liquid into the tubular member and discharging liquid from the tubular member via the liquid inlet/outlet are connected to the tubular member at the opening.

The foregoing amendments to claims 20 and 25 are supported throughout the specification. For example, the recitations of a tubular member having a liquid inlet/outlet and an opening, a base member contained through the opening of the tubular member and of means connected to the tubular member at the opening are supported by original claim 2 (now cancelled), Figure 2, and paragraphs [0025] and [0026] of the specification.

Claim 36 has been amended to correspond to the amendments to claim 25. None of the amendments to claims 20, 25 or 26 were made in response to rejections in the current Office Action, but rather, the amendments were made to enhance the Applicants' patent portfolio with claims of varying scope.

C. Rejection under 35 U.S.C. § 102(e) over Vann

Claims 15 – 19 stand rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,649,404 to Vann et al. ("Vann"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim ...". Applicant respectfully submits that Vann fails to satisfy

the criteria under MPEP § 2131 to support the present rejection of claims 15 – 19 under 35 U.S.C. § 102(e).

Claim 15 is independent, and is drawn to a device that includes a base member to which a plurality of detection substances is fixed. Each of the detection substances has a predetermined chemical structure. The base member has an unrolled configuration in which the detection substances are arranged in a predetermined order along the longitudinal length of the base member, and in which each pair of adjacent detection substances are spaced at a predetermined longitudinal spacing along the longitudinal length of the base member. The base member also has a rolled configuration in which the base member is rolled around a cylindrical structure to define a plurality of circumferentially-extending rolls, and in which each detection substance is exposed outwards and fixed to the base member at a predetermined fixed position relative to the outer surface of the cylindrical structure. In the rolled configuration, each pair of adjacent rolls in the plurality of circumferentially-extending rolls is spaced at a predetermined axial spacing along the longitudinal axis of the cylindrical structure. Further, each predetermined fixed position of the detection substances is defined by the predetermined order along the longitudinal length of the base member, the predetermined longitudinal spacings along the longitudinal length of the base member, and the predetermined axial spacings along the longitudinal axis of the cylindrical structure.

Each of claims 16 – 19 depends directly or indirectly from claim 15, and therefore each of claims 16 – 19 includes all of the foregoing elements.

In contrast, Vann does not disclose, motivate or suggest all of the elements of claim 15. Rather, Vann describes a fiber array 100 that is made of a support plate 102 having channels 108 formed therein by a plurality of channel walls 106. (col. 9, lines 39 – 42). Fibers 110 are disposed on the channel walls so that each fiber is physically separated from its adjacent fiber. (col. 9, lines 53 – 54). The fibers are arranged essentially parallel to each other and perpendicular to the channels. (col. 9, lines 55 – 56). The fibers have a chemical species immobilized on them. The channels receive a mobile chemical species. The mobile chemical species in the channel contacts the immobilized chemical species on the fiber. (col 5, lines 49 – 51). Interaction – if any –

caused by contact between the two chemical species is then analyzed. (col. 11, lines 67 – col. 12, line 2).

The current Office Action fails to point out elements of the fiber array described by Vann that correspond to each and every element of claims 15 – 19. However, it appears that the fibers 110 with a chemical species immobilized on them have been considered to be the equivalent of the base member to which a plurality of detection substances is fixed. Applicants respectfully submit that the fibers described by Vann are simply not the equivalent of the base member recited in claims 15 – 19 because the fibers described by Vann have neither the rolled nor the unrolled configurations recited in claims 15 – 19.

Vann is devoid of disclosure, motivation or suggestion for arranging detection substances in a predetermined order and spacing along the longitudinal length of a base member in an unrolled configuration. The predetermined order and spacing in the unrolled configuration of the base member of claims 15 – 19 directly affects the rolled configuration of the base member of claims 15 – 19. In particular, when the base member is in a rolled configuration around a cylindrical structure, then each detection substance is fixed to the base member at a predetermined fixed position relative to the cylindrical structure. The predetermined fixed position is defined in part by the predetermined order and spacing in the unrolled configuration. Vann is entirely lacking in disclosure, motivation or suggestion for using a predetermined order and spacing of detection substances along the longitudinal length of a base member in an unrolled configuration to position the detection substances when the base member is in a rolled configuration.

Furthermore, Vann does not disclose, motivate or suggest rolling a base member around a cylindrical structure such that a plurality of circumferentially-extending rolls are defined, such that each pair of circumferentially-extending adjacent rolls are spaced at a predetermined axial spacing along the longitudinal axis of the cylindrical structure, and such that each detection substance on the rolled base member is exposed outwards and fixed to the base member at a position relative to the outer surface of the cylindrical structure. Applicants note the reference in the Office Action to Figure 18 of Vann, but

respectfully submit that neither the Office Action nor Figure 18 set forth elements that correspond to each and every element of claims 15 – 19.

Fig. 18 of Vann shows a fiber array reader for reading long fiber arrays. (col 20, lines 36 – 37). Vann describes rolling the fiber array onto a hub 1818 in a format "similar to a typical audio-cassette tape." (col. 20, 37 – 39). The fiber array is then moved from hub 1818 to hub 1820 in a manner such that each fiber 110 can be read as it passes under a detector 1826. (col. 20. lines 42 – 43). To the extent that either hub 1818 or 1820 could be considered to be a cylindrical structure, and again, to the extent that a fiber could be considered to be a base member, the rolling of the fiber array onto a hub in the manner described by Vann will result in neither circumferentially-extending rolls, nor pairs of adjacent circumferentially-extending rolls that are spaced at a predetermined axial spacing along the longitudinal axis of a cylindrical structure.

As noted above, Vann describes rolling the fiber array onto a hub in a format "similar to a typical audio-cassette tape." Anyone viewing an audio-cassette tape will readily notice that the tape is not wound onto the hub in a manner that results in circumferentially-extending rolls, or pairs of adjacent circumferentially-extending rolls that are spaced at a predetermined axial spacing. Rather, an audio-cassette tape is wound in a manner that results in concentric circles of increasing diameter around the hub. There is no disclosure, motivation or suggestion in the illustration of Fig. 18 or the written description of Fig. 18 of any other type of rolled configuration, much less to the rolled configuration recited in claim 15.

Moreover, claims 15 – 19 require that when the base member is in a rolled configuration, each detection substance on the base member is exposed outwards and fixed to the base member at a position relative to the outer surface of the cylindrical structure. The rolling of a fiber array on a hub as described by Vann does not result in outward exposure of *each of* the chemical species fixed on the fibers in the array, nor the fixation of the chemical species at a position on the base member relative to the hub. To the contrary, rolling a fiber array on a hub as described by Vann results in a "layering" or "stacking" of the chemical species fixed on the fibers of the array. This "layering" or "stacking" is what requires the array to be transitioned from one hub to

another in order for a fiber to be read as it passes under a detector during such transition.

In view of the foregoing, Applicants respectfully submit that Vann fails to satisfy the criteria required under MPEP § 2131 to support the present rejection of claim 15 under 35 U.S.C. § 102(e) because Vann fails to disclose, motivate or suggest all of the elements of claim 15. Applicants also submit that the rejection of claims 16 – 19 under 35 U.S.C. § 102(e) over Vann cannot be supported for at least the same reasons that apply to claim 15. Applicants further submit that Vann fails to disclose, motivate or suggest the additional elements of claims 16 – 19. Accordingly, Applicants respectfully request that the rejection of claims 15 – 19 under 35 U.S.C. § 102(e) over Vann be withdrawn.

D. Rejection under 35 U.S.C. § 103(a) over Heynecker and Walt

Claims 15 – 33 and 36 – 42 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,057,100 to Heynecker ("Heynecker") in view of U.S. Patent No. 6,482,593 to Walt et al. ("Walt"). This rejection is respectfully traversed.

Heynecker describes an oligonucleotide array prepared as linear rows, "stripes", on a support surface, such as fibers. (col. 4, lines 24 – 47). The array can be used to detect target sequences. (col. 8, lines 29 – 30). In one embodiment, the array is in a circular form. (col. 6, lines 14 – 18 and Fig. 3).

Walt describes a fiber optic array made up of fiber strands S1 – S120. (col. 11, lines 8 – 12). Nucleic acid probes are attached to the end faces of the fiber strands. (col. 15, lines 15 – 20). The nucleic acid probes will react with a target sequence in a fluid sample so that the target sequence can be detected. (col. 18, lines 30 – 43).

To sustain the present rejection of claims 15 – 33 and 36 – 42 under 35 U.S.C. § 103(a), Heynecker and Walt must establish a prima facie case of obviousness. MPEP § 2142 provides that a prima facie case of obviousness requires three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the

claim limitations. In the present case, none of the criteria set forth in MPEP § 2142 have been satisfied with respect to independent claims 15 and 25, nor the claims dependent thereon.

1. Claims 15 and 16 – 24

Claim 15 is independent, and is drawn to a device that includes a base member to which a plurality of detection substances is fixed. Each of the detection substances has a predetermined chemical structure. The base member has an unrolled configuration in which the detection substances are arranged in a predetermined order along the longitudinal length of the base member, and in which each pair of adjacent detection substances are spaced at a predetermined longitudinal spacing along the longitudinal length of the base member. The base member also has a rolled configuration in which the base member is rolled around a cylindrical structure to define a plurality of circumferentially-extending rolls, and in which each detection substance is exposed outwards and fixed to the base member at a predetermined fixed position relative to the outer surface of the cylindrical structure. In the rolled configuration, each pair of adjacent rolls in the plurality of circumferentially-extending rolls is spaced at a predetermined axial spacing along the longitudinal axis of the cylindrical structure. Further, each predetermined fixed position of the detection substances is defined by the predetermined order along the longitudinal length of the base member, the predetermined longitudinal spacings along the longitudinal length of the base member, and the predetermined axial spacings along the longitudinal axis of the cylindrical structure.

Each of claims 16 – 24 depends directly or indirectly from claim 15, and therefore each of claims 16 – 24 includes all of the foregoing elements.

As noted above, claim 15 requires a base member having an unrolled configuration in which detection substances fixed to the base member are in a predetermined order and spacing along the longitudinal length of the base member. The predetermined order and spacing in the unrolled configuration of the base member directly affects the rolled configuration of the base member. In particular, when the base member is in a rolled configuration around a cylindrical structure, each detection

substance is fixed to the base member at a predetermined fixed position relative to the cylindrical structure. The predetermined fixed position is defined in part by the predetermined order and spacing, which are determined by the unrolled configuration. Heynecker is entirely lacking in disclosure, motivation or suggestion for using a predetermined order and spacing of detection substances along the longitudinal length of a base member in an unrolled configuration to position the detection substances when the base member is in a rolled configuration.

Furthermore, Heynecker does not disclose, motivate or suggest rolling a base member around a cylindrical structure such that a plurality of circumferentially-extending rolls are defined, such that each pair of circumferentially-extending adjacent rolls are spaced at a predetermined axial spacing along the longitudinal axis of the cylindrical structure, and such that each detection substance on the rolled base member is exposed outwards and fixed to the base member at a position relative to the outer surface of the cylindrical structure. Applicants note the reference in the Office Action to Figure 3D of Heynecker as allegedly showing the rolled configuration described in claims 15 – 24. Thus, it appears that the array described by Heynecker has been considered to be the equivalent of the base member recited in claims 15 – 24. Applicants respectfully submit that neither the illustration of Figure 3D or the written description thereof discloses, motivates or suggests all of the elements of claims 15 – 24.

The array illustrated in Figure 3D of Heynecker is a composite array, formed by associating a plurality of circular arrays. (col. 6, lines 22 – 23). Applicants recognize that the term "comprising" in the preamble of claim 15 makes it possible for the device of claim 15 to include a plurality of base members, just as the composite array illustrated in Figure 3D of Heynecker includes a plurality of circular arrays. However, recitation in claim 15 of "a base member" that has an unrolled and a rolled configuration requires that every base member in the claimed device, regardless of number, have a rolled and unrolled configuration as described therein. Thus, even if multiple base members were present, each base member would have a rolled configuration around a cylindrical structure that results in circumferentially-extending rolls, wherein pairs of adjacent circumferentially-extending rolls are spaced at a predetermined axial spacing

along the longitudinal axis of the cylindrical structure. Heynecker does not even illustrate or describe a cylindrical structure around which to form a rolled configuration, and even if such disclosure were present, Heynecker would still fail to disclose, motivate or suggest the particular rolled configuration recited in claim 15.

Moreover, claim 15 requires that when the base member is in a rolled configuration, each detection substance on the base member is exposed outwards and fixed to the base member at a position relative to the outer surface of the cylindrical structure. The fixed position relative to the outer surface of the cylindrical structure is defined at least in part by the predetermined order and longitudinal spacing of the detection substances on the base member in an unrolled configuration. Heynecker is completely devoid of disclosure, motivation or suggestion for locating oligonucleotides (which appear to have been equated with the detection substances of claim 15) in a predetermined order and longitudinal spacing on an array (which appears to have been equated with the base member of claim 15) such that when the array is in a rolled configuration (which is alleged in the Office Actin to be shown in Fig. 3D), the position of the oligonucelotides is defined by a predetermined order and longitudinal spacing of the oligonucleotides on the array in an unrolled configuration.

Walt does not provide the disclosure, motivation or suggestion that is missing in Heynecker with respect to claim 15. Walt is entirely lacking in disclosure, motivation or suggestion for using a predetermined order and spacing of detection substances along the longitudinal length of a base member in an unrolled configuration to position the detection substances when the base member is in a rolled configuration. Even if a fiber strand as described by Walt could be considered to be a base member as recited in claim 15, the nucleic acid probes (to the extent they can be considered as "detection substances") are positioned on the *end face* of the fiber strand, and not spaced along the longitudinal length of the fiber strand in a predetermined order. (col. 15, lines 14 – 15; col. 18, lines 33 and 43). Thus, it would be impossible for the fiber strands described by Walt to have a rolled configuration around a cylindrical structure in which each nucleic acid would be fixed to the base member at a predetermined fixed position defined in part by the predetermined order and spacing of the unrolled configuration.

Furthermore, Walt does not even disclose, motivate or suggest rolling a fiber strand around a cylindrical structure, much less rolling a fiber strand around a cylindrical structure to define a plurality of circumferentially-extending rolls that are spaced at a predetermined axial spacing along the longitudinal axis of the cylindrical structure. Further still, Walt cannot disclose, motivate or suggest that each nucleic acid on a rolled fiber strand would be exposed outwards.

In view of the foregoing, Applicants respectfully submit that neither Heynecker nor Walt, alone or in combination, discloses, motivates or suggests all of the limitations of claim 15. Accordingly, at least one of the elements required for a prima facie case of obviousness has not been shown with respect to claim 15, and therefore the entire prima facie case must fail.

The prima facie case against claims 16 – 24 must also fail for at least the same reasons that apply to claim 15. Furthermore neither Heynecker nor Walt, alone or in combination, discloses, motivates, or suggests all of the additional limitations of claims 16 – 24.

Applicants further submit that the remaining two criteria of the prima facie case are also unsatisfied. There is no suggestion or motivation, either in Heynecker or Walt, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. In addition, there is no reasonable expectation of success for such a modification or combination, for at least the very reason that the references, either alone in combination, do not disclose, motivate or suggest all of the limitations of claim 16 – 24.

2. Claims 25 and 26 – 42

Claim 25 is drawn to a device comprising a tubular member having a liquid inlet/outlet and an opening, a base member contained through the opening of the tubular member, and a source of a liquid comprising at least one target substance. A plurality of detection substances are fixed to the base member at predetermined fixed positions. Means are connected at the opening of the tubular member for drawing liquid from the source into the tubular member, and discharging the liquid from the tubular member via the liquid inlet/outlet. The device further comprises means positioned

outside of the tubular member for identifying the target substance after the target substance has reacted with a corresponding one of the detection substances. In particular, means for receiving emissions propagating through the wall of the tubular member and from the predetermined fixed positions.

Each of claims 26 – 42 depends directly or indirectly from claim 25, and therefore each of claims 26 – 42 includes all of the foregoing elements.

In contrast, neither Heynecker nor Walt, alone or in combination, discloses, motivates or suggests all of the foregoing limitations.

Applicants note the statement in the Office Action that Heynecker shows rotating the disks of Fig. 3D through a test solution, and the allegation that a container in which the test solution is contained could be a tubular member. Applicants further note the statement in the Office Action that "it would have been obvious to one of ordinary skill in the art that the test solution would have to be put into and drawn out of the container by some means, although the particular means is not specifically disclosed." (Office Action, p. 7).

Applicants respectfully submit, however, that Heynecker does not disclose, motivate or suggest a device that includes a tubular member having a liquid inlet/outlet and an opening, a base member contained through the opening and disposed in a tubular member, a source of a liquid comprising at least one target substance, and means connected to the tubular member at the opening for drawing liquid from the source into the tubular member, and for discharging the liquid from the tubular member via the liquid inlet/outlet. Even if Heynecker described rotating the disks of Fig. 3D in a tubular container holding a test solution, such a device does not disclose, motivate or suggest means connected at the opening of a tubular member for drawing the test solution from a source and into the container. The device described by Heynecker provides only for rotation of disks through a test solution, not for drawing a liquid with a target substance therein from a source into a tubular member where a base member is disposed.

Furthermore, Heynecker does not disclose, motivate or suggest a device that includes means for identifying the target substance after the target substance has reacted with a corresponding one of the detection substances on the base member,

wherein the identifying means receives signals (emissions) through the wall of the tubular member. In contrast, the only identification means described by Heynecker is to use a laser to detect fluorescent labels on the array, similar to reading a bar code. (col. 6, lines 35 – 38). This description does not disclose, motivate or suggest a device that includes identifying means that receives signals (emissions) through the wall of the tubular member to identify a target substance therein.

Walt does not provide the disclosure, motivation or suggestion that is missing in Heynecker with respect to claim 25. Walt describes nucleic acid probes positioned on a distal end face of fiber strands. When the nucleic acid probes are contacted with a solution containing labeled target sequences, the labeled target sequences become immobilized at the contact location. The label will emit light, thereby indicating its presence, and the presence of the target sequence. The light is conveyed via the fiber strand to which the labeled target sequence was immobilized, and emerges from the other end surface at a precisely located spatial position corresponding to the location of the probe on the distal end face. (col 22, lines 30 – 60). The nucleic acid probes contact the solution of labeled target sequences by being placed therein. (See e.g., col. 29, lines 58 – 60; col. 30, lines 37 – 38; col. 31, lines 28 – 30; col. 31, lines 55 – 56).

In contrast, claim 25 recites a device that includes a base member disposed in a tubular member, a source of a liquid comprising at least one target substance, and means connected to the tubular member for drawing liquid from the source into the tubular member, and for discharging the liquid from the tubular member. Walt is completely devoid of disclosure, motivation, or suggestion for such a device.

Furthermore, Walt does not disclose, motivate or suggest a device that includes means for identifying the target substance after the target substance has reacted with a corresponding one of the detection substances on the base member, wherein the identifying means receives signals (emissions) through the wall of the tubular member. In contrast, the only identification means described by Walt is the apparatus illustrated in Fig. 14. (col 27, lines 1 – 55). This description does not disclose, motivate or suggest a device that includes identifying means that receives signals (emissions) through the wall of a tubular member, as recited in claim 25, to identify a target substance therein.

In view of the foregoing, Applicants respectfully submit that neither Heynecker nor Walt, alone or in combination, discloses, motivates or suggests all of the limitations of claim 25. Accordingly, at least one of the elements required for a prima facie case of obviousness has not been shown with respect to claim 25, and therefore the entire prima facie case must fail.

The prima facie case against claims 26 – 42 must also fail for at least the same reasons that apply to claim 25. Furthermore neither Heynecker nor Walt, alone or in combination, discloses, motivates, or suggests all of the additional limitations of claims 26 – 42.

Applicants further submit that the remaining two criteria of the prima facie case are also unsatisfied. There is no suggestion or motivation, either in Heynecker or Walt, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. In addition, there is no reasonable expectation of success for such a modification or combination, for at least the very reason that the references, either alone in combination, do not disclose, motivate or suggest all of the limitations of claim 26 – 42.

Furthermore, according to the present device, contamination of the base member is avoided because a liquid can be drawn and discharged via the liquid inlet/outlet by the means connected to the tubular member at the opening, while the base member remains contained in the tubular member. In contrast, in a device where a base member is contained in a usual container having only one opening, discharge of a liquid requires that the container be tilted relevant to the amount of liquid in the container (the less liquid in the container, the more tilt required). This configuration makes it difficult to empty such a container completely. In fact, to empty such a container completely requires methods likely to cause contamination by contact, for example, the use of a pipetting device which must be moved between the containers and is likely to contact the base member and/or container, thereby causing contamination.

Conclusion

Claims 15 – 44 are now pending in the present application. In view of the foregoing remarks, allowance of claims 15 – 44 is respectfully requested.

The examiner is invited to call the undersigned at the below-listed telephone number if a telephone conference would expedite or aid the prosecution and examination of this application.

Respectfully submitted,

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